

REMARKS

Claims 12-17, 19, and 21-33 are pending in the application. Claims 22-31 are withdrawn. Claims 12-17, 19, 21, 32 and 33 have been examined and are rejected. No claims are allowed.

In the present amendment new claims 34-40 have been added, and claims 12, 13, 19, 21 and 32 have been canceled. Claims 14-16, and 33 have been amended to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Support for the amendments and new claims can be found at least at page 3, penultimate paragraph; page 4, first and second paragraph; page 9, penultimate paragraph; page 10, first paragraph; page 11, penultimate paragraph; page 14, last paragraph; page 15, second paragraph; page 43, second paragraph; page 43, the section beginning "Preparation of the supercritical-CO₂-extract used in the experiments ("SC-extract")", and; in the claims as originally filed.

The newly presented composition claims recite the same special technical feature as the method-of-use claims currently under examination, i.e., the two specific extracts of *Argania spinosa* fruit.

No new matter has been added by this amendment. Entry and reconsideration of the rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

A. Claims 12, 13, 19, 32 and 33 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Charrouf et al. (1991), in view of Laigneau et al. According to the Office Action Charrouf teaches a lipidic extract of *Argania spinosa* using hexane and isolation of the unsaponifiable fraction of the hexane extract. It is acknowledged that Charrouf does not teach a method of treating skin damaged by UV-A comprising the lipophilic extract. Laigneau is joined for teaching a composition for application to skin which contains the unsaponifiable fraction of sesame oil mixed with one or more unsaponifiable fractions from any vegetable oil for preventing or treating the effects of UV-A on the skin. Applicants respectfully traverse this basis for rejection.

As amended, the claims recite revitalizing skin, stimulating skin metabolism or protecting skin from UV-A and UV-B radiation using either of two specific extracts of *Argania spinosa* fruit:

- (i) an ethanol/supercritical CO₂ extract comprising triterpenes esterified with fatty acids, or
- (ii) an unsaponifiable triterpene fraction consisting essentially of lupeol, α -amyryne, β -amyryne, taraxasterol and psi-taraxasterol.

To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Although the analysis need not identify explicit teachings directed to the claimed subject matter, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007). As such, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Furthermore, a proper rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

Charrouf discloses three fractions obtained from the unsaponifiable fraction of an *Argania spinosa* hexane extract. Page 4, lines 3-8, of the translation. Fraction A contains triterpenic alcohols and Fraction C contains erythrodiol. As noted in the Office Action, Charrouf does not teach or suggest use of any of the fractions for treating skin.

Fraction A of Charrouf generally corresponds to Applicants' Fraction A, which is also a triterpene fraction. Fraction C of Charrouf generally corresponds to Applicants' Fraction C, which consists of pure erythrodiol. Applicants' disclose that Fraction A contains certain specific compounds (lupeol, α -amyrine, β -amyrine, taraxasterol and psi-taraxasterol). *Page 43, lines 5-13, of the Substitute Specification.* The triterpene erythrodiol is therefore removed from the triterpenes in Fraction A.

According to the claimed invention, it has been unexpectedly found that Fraction A has advantages for revitalizing skin, stimulating skin metabolism or protecting skin from UV-A and UV-B radiation that are not found in Fraction C. The Table on page 44 of the specification presents results of a comparison of cell growth and toxicity of Fraction A (triterpene fraction) with Fraction C (erythrodiol). Cell growth is expressed as % growth compared to untreated controls. Toxicity is expressed as LD50 (%w/v) based on exposure of cultured fibroblasts to varying concentrations of the test substance. The results show that the triterpene Fraction A promotes cell growth and is less toxic than the erythrodiol Fraction C, i.e., it has a higher LD50. In comparison, erythrodiol Fraction C does not promote cell growth. *See also paragraph bridging pages 44 and 45.* These experiments demonstrate a significant, unexpected difference between Fraction A and Fraction C with respect to biological activities related to revitalizing skin and stimulating skin metabolism.

Further, experiments demonstrating cytophotoprotection of human keratinocytes against UV-B radiation using Fraction A and Fraction C are disclosed in Example 4. *Page 48-50 of the Substitute Specification.* These experiments evaluated the release of prostaglandins, which are associated with redness and swelling after sunburn. Cell viability was measured by cell number and LDH release. Results for the two fractions were compared to unirradiated control (Control – not irradiated) and to an irradiated control without treatment (Control/UVB). The Table on page 50 presents the results. It can be seen that triterpene Fraction A distinctly reduced UV-induced toxic effects on cell viability (i.e., a smaller reduction in cell number and less LDH release vs. Control/UVB). In addition, triterpene Fraction A significantly reduced the release of the inflammatory mediator prostaglandin 2 (i.e., less PGE2 release vs. Control/UVB). In contrast,

erythrodiol Fraction C had no effect on the reduction in cell number, increased the release of LDH and increased the release of PGE2 (compare UVB+erythrodiol to Control/UVB). *See also Page 50, last paragraph, and page 51, first paragraph.* These results demonstrate a significant, unexpected difference between Fraction A and Fraction C with respect to biological activities related to protecting skin from UV radiation.

Example 2 (beginning on page 45 of the Substitute Specification) presents experimental data relating to the toxicity and regenerating/revitalizing activity of Fraction A (triterpene fraction), Fraction C (erythrodiol) and an ethanol/supercritical CO₂ extract (SC-extract) on human fibroblasts. Levels of ATP, GSH, proteins and DNA in response to varying concentrations of the extracts were measured as markers for these activities. Triterpene Fraction A and the SC-extract significantly enhanced the amount of DNA, ATP and proteins (including GSH) in fibroblasts, indicating stimulation of cell metabolism. In contrast, erythrodiol Fraction C showed no activity except for an increase in GSH only at a concentration of 0.00003%. *See Table on page 46 of the Substitute Specification, and the three paragraphs following the Table.*

As discussed above, Charrouf does not teach or suggest any skin-related use for any of the individual fractions of the hexane extract that are disclosed. Charrouf also does not teach or suggest an ethanol/supercritical CO₂ extract of *Argan spinosa* fruit. Laigneau provides no teaching with respect to *Argania spinosa* extracts or their components and therefore cannot provide the teaching missing from Charrouf. In view of the unexpected results associated with the ethanol/supercritical CO₂ extract comprising triterpenes esterified with fatty acids and the unsaponifiable triterpene fraction consisting essentially of lupeol, α -amyrine, β -amyrine, taraxasterol and psi-taraxasterol as discussed above, independent claim 34 is not *prima facie* obvious. Where an independent claim is valid over cited art, a fortiori any claim dependent therefrom must also be valid over the same art. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1576 n.36 (Fed. Cir. 1987). Withdrawal of the rejection of claim 34 and claims dependent thereon is respectfully requested.

New independent composition claims 35 and 40, and claims dependent thereon, recite the non-obvious extracts discussed above in connection with the method-of-use claims. These claims are therefore also not *prima facie* obvious.

B. Claims 12-17, 19, 21, 32 and 33 are rejected as allegedly unpatentable over Charrouf 1991 and Laigneau as applied above, and further in view of Charrouf 2 (EP1213025). Charrouf 2 is joined for teaching cosmetic or dermatological preparations for skin and/or hair containing amounts of *Argania spinosa* leaf extract as claimed. Applicants respectfully traverse this basis for rejection.

Charrouf 2 also fails to teach or suggest the use of any specific fraction of the extracts used in the disclosed compositions. Charrouf 2 therefore fails to remedy the deficiencies of the primary references as discussed above, particularly in view of Applicants' unexpected results with respect to the claimed ethanol/supercritical CO₂ extract comprising triterpenes esterified with fatty acids and the unsaponifiable triterpene fraction consisting essentially of lupeol, α -amyrine, β -amyrine, taraxasterol and psi-taraxasterol as discussed above. New independent claim 34 and claims dependent thereon, as well as new claims 35 and 40, and claims dependent thereon, are therefore not *prima facie* obvious.

CONCLUSION

It is believed that claims 14-17 and 33-40 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due with this submission. If any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

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RCE & AMENDMENT / RESPONSE UNDER 37 CFR § 1.114

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